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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/338, 063	06/23/99	GOTO	M FJN-060DV2 (3

021323  
TESTA HURWITZ & THIBEAULT  
HIGH STREET TOWER  
125 HIGH STREET  
BOSTON MA 02110

HM12/0210

EXAMINER	
EWOLDT, G	
ART UNIT	PAPER NUMBER

1644

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**DATE MAILED:** 02/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/338,063</b>	Applicant(s) <b>Goto et al.</b>
	Examiner <b>Gerald Ewoldt</b>	Group Art Unit <b>1644</b>

Responsive to communication(s) filed on 6/23/99 and 12/16/99.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 32-36 is/are pending in the application.

Of the above, claim(s) 36 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 32-35 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) 1/915,004 filed 8/20/99.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**DETAILED ACTION**

1. This application is a division of application Serial No. 08/915,004 which is a CIP of PCT/JP96/00374.

2. Claims 32-36 are pending.

3. Applicant's election of Group I, Claims 32-35, in Paper No. 7, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claim 36 is withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 32-35 are being acted upon.

5. The preliminary amendment, filed 6/23/99, to the Abstract and the Specification has not been entered. A substitute specification, excluding claims, is required pursuant to 37 CFR 1.125(a) because of the excessive number of changes included in the preliminary amendment filed 6/23/99 (Paper No. 3). The preliminary amendments to the claims have been entered and are being acted upon.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

7. The abstract of the disclosure is objected to because of the use of the use of "said". Further, the abstract is required to be a single paragraph. Correction is required. See MPEP § 608.01(b).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

9. Claim 35 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The molecular weight of "about 150,000" has no antecedent basis in base claim 32.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 32-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Simonet et al. (1997).

Simonet et al. teach a 401 amino acid protein of approximately 60 kD which contains the claimed SEQ ID NOS: 1-3 and inhibits osteoclast differentiation. The reference also teaches polyclonal antibodies to said protein (see particularly Results).

The reference teaching clearly anticipates the claimed invention.

12. Claims 32-35 are rejected under 35 U.S.C. 102(a) as being anticipated by WO97/23614 (IDS).

WO97/23614 teaches a 401 amino acid protein of approximately 60 kD which contains the claimed SEQ ID NOS: 1-3 and inhibits osteoclast differentiation. The reference also teaches both polyclonal and monoclonal antibodies to said protein (see particularly Figures 9C-D and pages 32-33, Antibodies). Claim 35 is included because it would be an inherent property of a monoclonal antibody that it would have a molecular weight of about 150,000 D and be of the IgG<sub>1</sub>, IgG<sub>2a</sub>, or IgG<sub>2b</sub> subclass.

The reference teaching clearly anticipates the claimed invention.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Gerald R. Ewoldt, Ph.D.  
Patent Examiner  
Group 1640  
Technology Center 1600  
February 2, 2000

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